K130157

Aalto Scientific, Ltd.

510(k) Notification
Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set

MAR 19 2013

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008
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B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
Telephone: (760) 431-7922 Ext. 118
E-mail: dlyakov@aaltoscientific.com

C. Date of Summary Preparation

February 15, 2013

D. Device Identification

Product Trade Name:	Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set
Common Name:	Beta-Hydroxybutyric Acid Linearity
Classification Name:	Assay QC Material
Device Classification:	Class I, reserved
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJX

Device to Which Substantial Equivalence is Claimed

Product Trade Name:	Audit® MicroCV™ hs-CRP Linearity Set Aalto Scientific, Ltd., Carlsbad, CA K101427

E. Description of the Device

The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set is an assayed quality control material consisting of five levels of human based serum, with each level containing Beta-Hydroxybutyric Acid. It is used to confirm the proper calibration, linear operating range, and reportable range of Beta-Hydroxybutyric Acid. Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E.

F. Statement of Intended Use

The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set is an assayed quality control material consisting of five levels of human based serum. Each level contains Beta-Hydroxybutyric Acid. These five levels demonstrate a linear relationship to each other for

Beta-Hydroxybutyric Acid. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Beta-Hydroxybutyric Acid.

The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for Beta-Hydroxybutyric Acid. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set should not be used for calibration or standardization of the Beta-Hydroxybutyric Acid assay. The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set is "For In Vitro Diagnostic Use Only".

G. Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Open Vial Stability: Once a vial has been opened, the Beta-Hydroxybutyric Acid will be stable for 40 days when stored tightly capped at 2 - 8° C.

Shelf Life: Two years, when stored unopened at 2 - 8° C.
Note: Real time studies are ongoing to support the shelf life of this product.

H. Expected Values

Value assignment of Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set have been performed to determine the expected values of Beta-Hydroxybutyric Acid analyte. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Beta-Hydroxybutyric Acid, mmol/L, P-Modular Instrument, Roche Reagent									
Level A		Level B		Level C		Level D		Level E	
Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range
0.0	0.0	1.2	1.0-1.4	2.3	2.0-2.6	3.4	2.9-3.9	4.4	3.8-5.1

I. Technical Characteristics Compared to Predicate Device

Characteristics	Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set (New)	Audit™ MicroCV™ hs-CRP Linearity Set (K101427)
Intended Use	The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set is an assayed quality control material consisting of five levels of human based serum. Each level contains Beta-Hydroxybutyric Acid. These five levels demonstrate a linear relationship to each other for Beta-Hydroxybutyric Acid. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Beta-Hydroxybutyric Acid. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for Beta-Hydroxybutyric Acid. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set should not be used for calibration or standardization of the Beta-Hydroxybutyric Acid assay. The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set is "For In Vitro Diagnostic Use Only".	The Audit™ MicroCV™ hs-CRP Linearity Set is assayed quality control material consisting of five levels human based serum. Each level contains High Sensitivity C-Reactive Protein (hs -CRP) analyte. The five levels demonstrate a linear relationship to each other for High Sensitivity C-Reactive Protein (hs -CRP) analyte. It is intended to simulate human patient serum samples for purpose of monitoring and detecting systematic analytical deviations of laboratory testing procedures for High Sensitivity C-Reactive Protein (hs -CRP). This product may be used as quality control material for High Sensitivity C-Reactive Protein (hs -CRP) analyte. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling,The Audit™ MicroCV™ hs-CRP Linearity Set is "For In Vitro Diagnostic Use Only".
Number of Analytes per vial	1	1
Number of levels per set	5	5
Contents	5 x 1 mL	5 x 1 mL
Matrix	Human Based Serum	Human Based Serum
Type of Analytes	Beta-Hydroxybutyric Acid	High Sensitivity C-Reactive Protein
Form	Liquid	Liquid
Storage	2 to 8° C Until expiration date	2 to 8° C Until expiration date
Open Vial Stability	40 days at 2 to 8° C	20 days at 2 to 8° C

J. Conclusions

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2013

Aalto Scientific, Ltd
c/o Dessi Lyakov
1959 Kellogg Ave.
Carlsbad, CA 92008

Re: k130157
Trade/Device Name: Audit ® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: January 14, 2013
Received: February 06, 2013

Dear Dessi Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k130157

Device Name: Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set

Indications for Use:

The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set is an assayed quality control material consisting of five levels of human based serum. Each level contains Beta- Hydroxybutyric Acid. These five levels demonstrate a linear relationship to each other for Beta-Hydroxybutyric Acid. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Beta- Hydroxybutyric Acid.

The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for Beta-Hydroxybutyric Acid. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set should not be used for calibration or standardization of the Beta-Hydroxybutyric Acid assay. The Audit® MicroCV™ Beta- Hydroxybutyric Acid Linearity Set is "For In Vitro Diagnostic Use Only".

Prescription Use __X____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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